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DETAILED ACTION

Election/Restrictions

Claims 26-41 are withdrawn from further consideration pursuant to 37 CFR
 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 1/19/12.

Information Disclosure Statement

2. IDS filed on 5/22/06, 8/04/06, 10/03/07, 11/15/07, 1/14/10, and 11/18/11 has been considered.

Claim Objections

3. Claim 6 objected to because of the following informalities: There should be a closed parenthesis at the end of the function g in line 7 prior to the last comma.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 6. As to claim 1, it is unclear what having a temperature sensor "depend in a different manner on a skin temperature of the body and on an environmental temperature than a signal of the second sensor" means. Does the first sensor measure skin temperature whereas the second sensor measure environmental? Or do they both

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measure (or is influenced by) both, but are influenced differently to each? Clarification is required. For purposes of examination, it will be understood that the first sensor only measures skin temperature and the second only measures environmental temperature (as understood from [0054-0056]).

- 7. As to claims 6 and 12, it is unclear whether the recitation of a sensor arrangement and a processing circuitry is the same as claim 1 or in addition to.
- 8. As to claim 16, applicant is required to spell out what each variable means.
- 9. As to claim 24, it is unclear what "it" in line 2 is referring to, whether it is the holder or the device.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 1-3, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal (USP #5,077,476).
- 12. As to claim 1, Rosenthal teaches a device for measuring glucose level in a living body (Abs), said device comprising a sensor arrangement (8) to be applied to a surface of the body (Fig. 1), processing circuitry for measuring a response (10), and at least a first (29) and a second (27) temperature senor.
- 13. As to claim 2, Rosenthal teaches a first sensor closer to the sensor arrangement than the second sensor (Fig. 1)

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14. As to claim 3, Rosenthal teaches a housing (1) having a first and second side (Fig. 1 - left and right of imaginary line perpendicular to the tip of finger), the sensor and the first sensor arranged at the first side and the second sensor arranged at the second side.

- 15. As to claim 23, Rosenthal teaches that the measured signals comprise temperature sensor values (col. 6 lines 1-9).
- 16. As to claim 24, Rosenthal teaches a holder adapted to affix the device to the body (15).

Claim Rejections - 35 USC § 103

- 17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 18. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USP #5,077,476) in view of Say et al. (US 2003/0088166).
- 19. As to claim 4, Rosenthal does not teach that the first temperature sensor is in thermal contact with the sensor arrangement. However, Rosenthal shows that these two elements are lined up next to each other (Fig. 1) and that the sensor is applied to the surface of the body and that the temperature sensor measures skin temperature. Say, in teaching a glucose sensor, further teaches the use of a temperature probe that is in direct contact with the sensor arrangement ([0059-0060]). Such an arrangement would increase the accuracy of the device as the skin temperature measured would be a direct

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reflection of the measured location of glucose. As such, it would have been obvious to modify Rosenthal with Say to increase the accuracy of the device.

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- 20. Claim 6, 11-15, 17-19, 21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USP #5,077,476) in view of Goode, JR. et al (US 2005/0043598).
- 21. As to claims 6 and 18, Rosenthal fails to teach a function of calculating glucose level comprising input values, at least 1 calibration parameter, and determining the calibration parameters by comparing the values against reference values or values derived from reference values. However, Goode teaches the use of reference values to calibrate the input data ([0301-0315]) to determine glucose values ([0319]).
- 22. As to claim 11, Goode teaches the use of a plurality of algorithms ([0049]) to find an "optimum agreement" between the glucose levels calculated and the reference measurements.
- 23. As to claims 12 and 13, Goode teaches the detection of a shift in the measured glucose level and correcting the measured level to compensate ([0346], [0353]), said shift detected in a signal value from at least one of the input values.
- 24. As to claims 14 and 15, Goode teaches the determining of the shift by comparing an extrapolation of values prior to displacement to after displacement ([0353] the expected CV curve being an extrapolation of normal conditions), the comparison being a difference.

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25. As to claim 17, Goode teaches a predictor of calculating glucose levels wherein the derivative and the acceleration of the levels are within a certain value ([0024], [0087], [0249]), said predictor designed to designate the maximum rate of change or acceleration per unit time ([0387]).

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- 26. As to claim 19, Goode teaches an additive parameter in function F ([0390] add/subtract from the value to be within the cone).
- 27. As to claim 21, the measured input values are inherently indicative of a response of the sensor arrangement ([0057]).
- 28. As to claim 25, Rosenthal fails to teach an electrode based sensor. Goode teaches an electrochemical glucose sensor incorporating at least two electrodes

Allowable Subject Matter

- 29. Claims 5, 7-10, 20, and 22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, as well as 35 USC 101, set forth in this Office action.
- 30. As to claim 5, the prior art of record fails to teach a second temperature sensor in thermal contact with the assembly of electronic circuits.
- 31. As to claim 7, the prior art of record fails to teach the calculation of calibration parameters by minimizing a deviation of the values from a prediction of the glucose level derived from the reference values.
- 32. As to claim 10, the prior art of record fails to teach a means for replacing the calibration parameters by the recited equation.

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33. As to claim 20, the prior art of record fails to teach the calculating of glucose level g using the recited equation.

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34. As to claim 22, the prior art of record fails to teach the applying of a frequency sweep, detecting a characteristic frequency at the point at which a signal becomes a minimum.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Friday (9-5).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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CJ /C. J./ Examiner, Art Unit 3735 1/26/12

/Patricia Mallari/ Primary Examiner, Art Unit 3735